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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/500,296 | 06/28/2004 | Yuji Yamazaki | 081356-0218 | 7715 |

22428 7590 01/13/2006

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| EXAMINER | |
|---|---|
| RINAUDO, JO ANN S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/500,296 | YAMAZAKI ET AL. | |
| | Examiner | Art Unit | |
| | Jo Ann Rinaudo | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *8 and 10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-19 are pending.

2. Applicant's election without traverse of Group I (Claims 1-7 and 9) in the reply filed on 21 November 2005 is acknowledged.

3. Applicant has further elected the species of amino acid sequence represented by SEQ ID NO:1.

4. Claims 1-7 and 9 read on the elected species.

5. Claims 1-7 and 9 are under consideration in the instant application as they are drawn to an antibody obtained by immunizing an animal with an amino acid sequence represented by SEQ ID NO:1, an antibody which is produced by a hybridoma whose accession number is FERM BP-7838, FERM BP-7839, FERM BP-7840, or FERM BP-8268, and a pharmaceutical composition comprising said antibody.

6. Claims 3-7 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

8. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 5 and 6 are indefinite in the recitation of "ADHR" and "XLH". The terms are not defined in the claims. It is suggested that the claims be amended to recite "autosomal dominant hypophosphatemic rickets" and "X-linked hypophosphatemic rickets", respectively.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

11. Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody obtained by immunizing an animal with the polypeptide consisting of the amino acid sequence represented by SEQ ID NO:1 and has fibroblast growth factor-23 activity and the antibody which is produced by a hybridoma whose accession number is FERM BP-7838, FERM BP-7839, FERM BP-7840, or FERM BP-8268 (Claims 1 and 3); the said antibody which is a monoclonal antibody (Claim 2); a pharmaceutical composition of said antibody effective against osteoporosis and hypophosphatemia (Claims 4-7, and 9) *does not reasonably provide enablement for* an antibody obtained by immunizing an animal with polypeptides which comprise "an" amino acid sequence represented by SEQ ID NO: 1, or "an" amino acid sequence derived from the amino acid sequence represented by SEQ ID NO:1 by deletion, substitution, or addition of 1 or several amino acids, and has fibroblast growth factor-23 activity (Claims 1 and 3); the said antibody which is a monoclonal antibody (Claim 2); a pharmaceutical composition of said antibody effective against at least one disease selected from tumor-induced osteomalacia, ADHR, XLH, renal osteodystrophia, dialysis osteopathy, rickets, osteomalacia, dysfunction of the renal tubule, osteopenia, hypocalcemia, disorder of bone extension, disorder of bone calcification, hyperparathyroidism, ectopic calcification, itching, osteosclerosis, Paget's disease, hypercalcemia, hypoparathyroidism, ostealgia, decreased muscle force, skeletal deformation, failure to thrive, and hypovitaminosis D (Claims 4-6 and 9); and an agent for promoting osteogenesis, comprising the antibody as an active ingredient (Claim 7). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

12. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the amount of direction or guidance provided, the lack of sufficient working examples, and the amount of

experimentation required to enable one skilled in the art to practice the invention.

13. In Claim 1, "comprise **an** amino acid sequence represented by SEQ ID NO: 1" encompasses amino acid sequences that comprise the full-length sequence of SEQ ID NO:1 or any portion of SEQ ID NO:1. Further, the antibody is "derived from the amino acid sequence represented by SEQ ID NO:1 by deletion, substitution, or addition of 1 or several amino acids". The specification fails to provide guidance as to how to determine sequences other than the full-length sequence of SEQ ID NO:1 that still retain fibroblast growth factor-23 activity. It is known in the art that even single amino acid changes or differences in a protein's amino acid sequence can have dramatic effects on the protein's function. For example, Wen et al. teach that a mutation in PTEN (G129E), a phosphatase, impaired lipid phosphatase activity and angiogenesis. Given the lack of sufficient guidance and working examples, predicting what amino acid sequences will retain the same structure, function, and fibroblast growth factor-23 activity as SEQ ID NO: 1 is unpredictable. The skilled artisan cannot envision all the contemplated amino acid sequence possibilities that occur within the given sequences and have fibroblast growth factor-23 activity, other than the full-length sequence of SEQ ID NO:1. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

14. Claims 5-7 require that the pharmaceutical composition comprising the antibody is "effective against at least one disease" and "promoting osteogenesis". The specification only provides guidance for the use of the antibodies produced by the hybridomas whose accession numbers are FERM BP-7838, FERM BP-7839, FERM BP-7840, or FERM BP-8268 in the treatment of osteoporosis and hereditary hypophosphatemia in a mouse model (see pages 109-113, in particular). Applicant cannot extrapolate to all the diseases recited in claims 5-7, because they represent different groups of diseases. For example, skeletal deformations are a diverse group of diseases, as taught by Superti-Furga et al. (see page 282, Introduction, in particular). Superti-Furga et al. classify these skeletal diseases into 7 groups (see pages 284-287, Table 1, in particular). Group 4, Defects in hormones and signal transduction mechanisms, includes fibroblast growth factor-23 diseases (see page 285, in particular). Because skeletal deformations are diverse groups of diseases, treatment with an antibody against fibroblast

growth factor-23 would not treat ALL skeletal deformations and furthermore effectiveness of this treatment would be unpredictable. The skilled artisan cannot envision a pharmaceutical composition comprising the antibody which is effective against the diseases recited in Claims 5-7, other than osteoporosis and hereditary hypophosphatemia. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

15. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the lack of working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

16. The specification on page 51 and the declaration, filed on 28 June 2004 by the attorney Stephen Bent, that the hybridomas, with accession numbers FERM BP-7838, FERM BP-7839, FERM BP-7840, and FERM BP-8268, were deposited under the provisions of the Budapest Treaty and the statement that all restrictions on the availability to the public of the culture deposited *will be irrevocably* removed upon granting of a patent, is sufficient to satisfy the requirement for the deposit of the biological material under 35 U.S.C. 112 first paragraph.

17. Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

18. Applicant is in possession of an antibody obtained by immunizing an animal with the polypeptide consisting of the amino acid sequence represented by SEQ ID NO:1 and has fibroblast growth factor-23 activity and the antibody which is produced by a hybridoma whose accession number is FERM BP-7838, FERM BP-7839, FERM BP-7840, or FERM BP-8268 (Claims 1 and 3); the said antibody which is a monoclonal antibody (Claim 2); a pharmaceutical composition of said antibody effective against osteoporosis and hypophosphatemia (Claims 4-7, and 9).

19. Applicant is not in possession of an antibody obtained by immunizing an animal with polypeptides which comprise "an" amino acid sequence represented by SEQ ID NO: 1, or "an" amino acid sequence derived from the amino acid sequence represented by SEQ ID NO:1 by deletion, substitution, or addition of 1 or several amino acids, and has fibroblast growth factor-23 activity (Claims 1 and 3); the said antibody which is a monoclonal antibody (Claim 2); a pharmaceutical composition of said antibody effective against at least one disease selected from tumor-induced osteomalacia, ADHR, XLH, renal osteodystrophia, dialysis osteopathy, rickets, osteomalacia, dysfunction of the renal tubule, osteopenia, hypocalcemia, disorder of bone extension, disorder of bone calcification, hyperparathyroidism, ectopic calcification, itching, osteosclerosis, Paget's disease, hypercalcemia, hypoparathyroidism, ostealgia, decreased muscle force, skeletal deformation, failure to thrive, and hypovitaminosis D (Claims 4-6 and 9); and an agent for promoting osteogenesis, comprising the antibody as an active ingredient (Claim 7).

20. There is insufficient written description of "an antibody obtained by immunizing an animal with polypeptides which comprise an amino acid sequence represented by SEQ ID NO: 1, or an amino acid sequence derived from the amino acid sequence represented by SEQ ID NO:1 by deletion, substitution, or addition of 1 or several amino acids, and has fibroblast growth factor-23 activity". Therefore the skilled artisan cannot envision all the contemplated antibodies, as recited in the instant claims.

21. There is insufficient written description of a pharmaceutical composition effective against at least one disease selected from tumor-induced osteomalacia, ADHR, XLH, renal osteodystrophia, dialysis osteopathy, rickets, osteomalacia, dysfunction of the renal tubule, osteopenia, hypocalcemia, disorder of bone extension, disorder of bone calcification, hyperparathyroidism, ectopic calcification, itching, osteosclerosis, Paget's disease, hypercalcemia, hypoparathyroidism, ostealgia, decreased muscle force, skeletal deformation, failure to thrive, and hypovitaminosis D (Claims 4-6 and 9); and an agent for promoting osteogenesis, comprising the antibody as an active ingredient (Claim 7). The specification does not describe sufficient functional characteristics of pharmaceutical composition effective against the diseases, other than osteoporosis and hypophosphatemia. Therefore the skilled artisan cannot envision a pharmaceutical composition effective against all the diseases, as recited in

the instant claims.

22. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1"Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3rd column).

23. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

24. Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

*(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.*

26. Claims 1, 2, 4-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2002/01566001.

27. The '001 publication teaches an antibody that specifically binds with an FGF-23 polypeptide, or a mutant, variant, homolog or fragment thereof (see paragraph [0017], and Claim 20, in particular). The FGF-23 polypeptide in the '001 publication (SEQ ID NO: 2) has the same sequence as SEQ ID NO:1 of the instant application. The antibody is a monoclonal antibody (see paragraph [0017], and Claim 21, in particular). Further, the antibody is an inhibitor of FGF-23 (see paragraph [0020], in particular). The '001 publication also teaches a composition comprising an antibody that specifically binds with FGF-23 and a pharmaceutically-acceptable carrier (see paragraph [0024], in particular). Moreover, the '001 publication teaches that an inhibitor of FGF-23, which includes the antibody, can be used in a method of treating a hypophosphatemic disorder (see paragraph [0045], in particular). The hypophosphatemic disorders include X-linked hereditary rickets (XLH), hereditary hypophosphatemic rickets, autosomal dominant hypophosphatemic rickets (ADHR), and tumor induced osteomalicia (see paragraph [0046], in particular).

28. Claim 7 is rejected because an antibody is the same antibody irrespective of its intended use.

29. Therefore the reference teachings anticipate the claimed invention.

30. The claimed antibody recognizes amino acid sequence between the 180$^{th}$ and 194$^{th}$ or the 237$^{th}$ and 251$^{st}$ amino acid residues represented by SEQ ID NO:1. The antibody, taught by the '001 publication, binds with an FGF-23 polypeptide represented by SEQ ID NO:2 and is in a pharmatceutical composition used to treat the same diseases, such as autosomal dominant hypophosphatemic rickets (ADHR) and tumor induced osteomalicia. SEQ ID NO:2, of the '001 publication, is the same sequence as SEQ ID NO:1, of the instant application. Therefore the

antibody taught by the '001 publication would have the ability to bind to the amino acid sequences between the 180th and 194th or the 237th and 251st amino acid residues represented by SEQ ID NO:1 and treat the same diseases. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the claimed antibody and the reference antibody. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

31. Claims 1, 2, 4-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 01/61007 publication.

32. The '007 publication teaches the production of anti-FGF-23 polypeptide antibodies (see page 97, Example 4, in particular). The FGF-23 polypeptide in the '007 publication (SEQ ID NO: 2) has the same sequence as SEQ ID NO:1 of the instant application. The anti-FGF-23 polypeptide antibodies are selective binding agents that have specificity for one or more FGF-23 polypeptides (see page 49, lines 20-25, in particular). The anti-FGF-23 polypeptide antibodies can be monoclonal antibodies (see Claim 24, in particular). Further, the '007 publication teaches that the selective binding agent antagonizes FGF-23 polypeptide biological activity (see Claim 32) and a method of treating an FGF-23 polypeptide-related disease, condition, or disorder comprising administering to a patient an effective amount of a selective binding agent (see Claim 33, in particular). In addition, the '007 publication teaches a method of treating a medical condition with an antagonist of the biological activity of the FGF-23 polypeptide and the medical condition is autosomal dominant hypophosphatemic rickets (ADHR) (see Claims 49 and 50, in particular).

33. Claims 4-7 are rejected because an antibody is the same antibody irrespective of its intended use.

34. Therefore the reference teachings anticipate the claimed invention.

35. The claimed antibody recognizes amino acid sequence between the 180th and 194th or the 237th and 251st amino acid residues represented by SEQ ID NO:1. The antibody, taught in the '007 publication, binds with an FGF-23 polypeptide represented by SEQ ID NO: 2, which is the same sequence as SEQ ID NO:1 of the instant application. Furthermore, the antibody taught by the '007 publication is in a composition used to treat the same diseases, such as autosomal dominant hypophosphatemic rickets (ADHR). Therefore the antibody taught by the '007 publication would have the ability to bind to the amino acid sequences between the 180th and 194th or the 237th and 251st amino acid residues represented by SEQ ID NO:1 and treat the same diseases. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the claimed antibody and the reference antibody. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

36. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Lorenz-Depierux et al.

37. Lorenz-Depierux et al. teach the production of a polyclonal antibody against the peptide corresponding to residues 229-243 of human FGF23.

38. Therefore the reference teachings anticipate the claimed invention.

39. The claimed antibody recognizes amino acid seqeuence between the 237th and the 251st amino acid residues of SEQ ID NO:1. The antibody, taught by Lorenz-Depierux et al., binds with an FGF-23 polypeptide corresponding to residues 229-243. The amino acid sequences of the instant application and Lorenz-Depierux et al. are the same in the regions that overlap. Therefore, the claimed antibody and the antibody taught by Lorenz-Depierux et al., the antibody taught by Lorenz-Depierux et al. would have the ability to bind to a region with the same amino acid seqeuence. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the claimed antibody and the reference antibody. In the absence of evidence to the contrary, the burden is upon the

applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

40. Claims 1, 2, 4-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2004/0082506.

41. The '506 publication teaches an antibody that specifically binds with an FGF-23 polypeptide (see Claims 10 and 11, in particular). The FGF-23 polypeptide in the '506 publication (SEQ ID NO: 2) has the same sequence as SEQ ID NO:1 of the instant application. The antibody is a monoclonal antibody (see paragraph [0140], in particular). The '506 publication also teaches a pharmaceutical composition comprising said antibody as an active ingredient (see Claim 12, in particular). Moreover, the '506 publication teaches that the pharmaceutical composition or diagnostic agent comprising the antibody can be used for treating bone diseases which include Paget's disease and tumor-induced osteomalacia (see Claims 15-19, in particular).

42. Claims 4-7 and 9 are rejected because an antibody is the same antibody irrespective of its intended use.

43. Therefore the reference teachings anticipate the claimed invention.

44. The claimed antibody recognizes amino acid sequence between the 180$^{th}$ and 194$^{th}$ or the 237$^{th}$ and 251$^{st}$ amino acid residues represented by SEQ ID NO:1. The antibody, taught by the '506 publication, binds with an FGF-23 polypeptide represented by SEQ ID NO: 2, which is the same sequence as SEQ ID NO:1 of the instant application. Furthermore, the antibody taught by the '506 publication is in a pharmaceutical composition used to treat the same diseases, which include Paget's disease and tumor-induced osteomalacia. Therefore the antibody taught by the '506 publication would have the ability to bind to the amino acid sequences between the 180$^{th}$ and 194$^{th}$ or the 237$^{th}$ and 251$^{st}$ amino acid residues represented by SEQ ID NO:1 and treat the same diseases. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the claimed antibody and the reference antibody. In the absence of evidence to the

contrary, the burden is upon the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977).

45. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

46. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

47. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

48. Claims 1, 2, 4-7, and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 10-19 of Application No. 10/344,339.

49. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1, 2, 4-7, and 9 of the instant application recite an antibody obtained by immunizing an animal with polypeptides which comprise an amino acid sequence represented by SEQ ID NO:1 (Claims 1 and 2); and a pharmaceutical composition comprising said antibody for the treatment of diseases such as osteoporosis, Paget's disease and tumor-induced osteomalacia (Claims 4-7 and 9). In Application No. 10/344,339, the Claims 10-19 recite an antibody which reacts with the polypeptide represented by SEQ ID NO: 2 (Claim 10); a method

for producing the polypeptide (Claim 11); and a pharmaceutical composition containing the antibody as an active ingredient which is capable of regulating in vivo calcium metabolism, phosphate metabolism and effective against bone diseases which include osteoporosis, Paget's disease and tumor-induced osteomalacia (Claims 12-15); and an agent containing the antibody as an active ingredient (Claims 16-19). In addition, the polypeptide represented by SEQ ID NO: 2, in Application No. 10/344,339, is the same as SEQ ID NO: 1 of the instant application. Therefore the antibodies, taught by the Application No. 10/344,339, would have the ability to bind to the amino acid sequences between the 180$^{th}$ and 194$^{th}$ or the 237$^{th}$ and 251$^{st}$ amino acid residues represented by SEQ ID NO:1 of the instant application and treat the same diseases.

50. This is a provisional obviousness-type double patenting rejection.

51. Claims 1, 2, 4-7 and 9 are directed to an invention not patentably distinct from claims 10-19 of commonly assigned Application No. 10/344,339, for the reasons set forth above under the obviousness-type double patenting rejection.

52. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned Application No. 10/344,339, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

53. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

54. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

55. No claim is allowed.

56. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

57. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jo Ann Rinaudo, Ph.D.
Patent Examiner
01/05/2006

Christina Chan

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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